Remarks and Arguments

Claims 62 and 71 have been amended. New Claims 96-112 have been added.

Claims 62, 63, 69, 71, 72, 82, and 85-112 remain in the application.

Claims 63, 69, 71, 72, 82, and 85-95 have been held to be withdrawn from consideration.

The Claim amendments split the claimed subject matter into two sets of Claims: subject matter pertaining to hybrids is now in the first set of Claims (62, 63, 69, 71, 72, 82, and 85-95), and subject matter pertaining to varieties is in the second set of Claims (96-112).

Before the present amendment, independent Claims 62 and 71 had each referred in the alternative both to hybrids and to varieties.

Independent Claims 62 and 71 have now been amended to refer to hybrids.

New independent Claims 96 and 99 refer to varietals.

Other than separating subject matter pertaining to hybrids from subject matter pertaining to varieties, the language of new Claims 96-112 is intended to parallel that of Claims 62, 63, 69, 71, 72, 82, and 85-95.

A minor clarification has also been made to the language of part (g) of Claim 71. This amendment is intended as a clarification only, and is not intended to alter the scope of the Claim: "~~said~~ the selected herbicide-resistant . . . ."

Reexamination and reconsideration of the application, as amended, are respectfully requested.

Heading numbers below (e.g., the number "4" in the section immediately following) refer to the sections with the corresponding heading numbers in the April 9, 2007 Office Action.

4. The Non-Elected Process Claims Should be Rejoined After the Product Claims Have Been Allowed

New Claim 96 is consonant with previously-elected Group I.

Applicant respectfully submits that once the elected Claims to the rice plants have been allowed, the non-elected Claims directed to processes for making and using the rice plants should then be rejoined and examined in the same application. In particular, the Office's attention is respectfully directed to M.P.E.P. § 821.04, which provides for rejoinder of process Claims in such a case.

Note particularly that rejoinder under M.P.E.P. § 821.04 does not depend upon whether the original election was made with or without traverse.

Applicant interprets the Office's June 3, 2004, October 6, 2005, June 23, 2006, and April 9, 2007 comments on this point as agreeing with Applicant's position in principle.

These observations apply equally to newly-added Claims 97-112.

5. The § 102(b) and § 103(a) Rejections

Claim 62 was rejected under 35 U.S.C. § 102(b) as being anticipated by Terakawa, or in the alternative under 35 U.S.C. § 103(a) as being obvious over a proposed combination of Terakawa with two secondary references, Bernasconi and Hattori.

Four independent reasons have now been presented for withdrawing the prior art rejections. Alone, any one of the four reasons should suffice to overcome the prior art. Taken in combination, the four reasons compel a conclusion of novelty and nonobviousness.

The reasons given for distinguishing Terakawa in the May 13, 2003 Amendment, in the April 11, 2006 Request for Continued Examination, and in the December 26, 2006 Reply are still fully applicable. Three reasons given in these prior responses are summarized below. A new, fourth reason for distinguishing Terakawa is argued in detail below. Individually, each of these four arguments, standing alone, should suffice to overcome the prior art rejection. When all four

reasons are taken together, their cumulative effect compels a conclusion of novelty and nonobviousness:

- Terakawa's mutant rice was reported to be resistant only to one sulfonylurea herbicide, bensulfuron methyl. However, bensulfuron methyl does not normally inhibit the growth of rice plants. To the contrary, Terakawa acknowledged that bensulfuron methyl's "toxicity to rice is not severe." Indeed, bensulfuron methyl is a herbicide that is commonly and regularly applied to ordinary rice fields, i.e., to rice that is not "herbicide resistant." Rice is inherently resistant to bensulfuron methyl. Terakawa thus has dubious weight as a prior art reference.

- Independent Claim 62 refers to selection with a "herbicidally-effective imidazolinone" (parts (b) and (c)). Independent Claim 62 also requires resistance to five specified imidazolinone herbicides (part (e)). Terakawa is silent concerning resistance to any imidazolinones, and instead mentions resistance only to bensulfuron methyl, which is a sulfonylurea. Because resistance to imidazolinone herbicides would have been agronomically significant, one would expect Terakawa to have reported such resistance if it had in fact been expressed by Terakawa's mutant line. Terakawa's silence strongly implies that Terakawa's mutant line was not resistant to imidazolinone herbicides.

- The Terakawa paper is not enabling prior art, because the seeds it described are not commercially available.[1]

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[1]The comparative tests that had once been contemplated with the Terakawa seed obtained by the inventor (through academic channels, not commercial channels) have not been conducted, and are not expected in the near future. The inventor retired from his position as Professor at the Rice Research Station of Louisiana State University before the comparative tests could be conducted.

- The fourth argument (which is new, and is explained further below) is that the Office has not made the stringent showing that would be required to support its contention that the Terakawa paper inherently discloses resistance to imidazolinone herbicides.

The Office has not made the stringent showing that would be required to support its contention that Terakawa inherently discloses resistance to imidazolinone herbicides.

The April 9, 2007 Office Action at p. 2 stated (citations omitted): "Claim 62 remains rejected under 35 U.S.C. § 102(b) as anticipated by, or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Terakawa taken with the evidence of Bernasconi and Hattori. This rejection is repeated for the reason of record as set forth in the last Office action mailed 23 June 2006."

Terakawa disclosed a mutant rice strain that was reported to be resistant to bensulfuron methyl, which is a sulfonylurea herbicide. Independent Claim 62 refers to selection with a "herbicidally-effective imidazolinone" (parts (b) and (c)). Independent Claim 62 also requires resistance to five specified imidazolinone herbicides (part (e)).

Nothing in Terakawa even hints that Terakawa's rice plants were resistant to a single imidazolinone herbicide. Because resistance to imidazolinone herbicides would have been agronomically significant, one would expect Terakawa to have reported such resistance if it had in fact existed in Terakawa's mutant line. Terakawa's silence on this point strongly implies that Terakawa's mutant line was not resistant to imidazolinone herbicides.

The Office has nevertheless contended that Terakawa's rice plants were inherently resistant to imidazolinones:

> Bernasconi *et al* provide evidence that a single point mutation can confer broad range tolerance to herbicides that target acetolactate synthase (see page 17381). Hattori *et al* provide evidence that separate mutations can produce multiple resistance to sulfonylureas and imidazolinones (see entire document). Applicant has provided no evidence that the herbicide-resistant

> rice plants disclosed by Terakawa *et al* do not inherently have the herbicide-resistant "fingerprint" of the instant claimed rice plant. While Terakawa *et al* are silent as to the imidazolinone resistance and the type of sulfonylurea resistance of the disclosed herbicide resistant rice plants, it is clear that imidazolinone resistance is inherent in mutant plants as evidence by the prior art.

(June 23, 2006 Office Action, p. 5, last paragraph)

The Office appears to be contending that Terakawa inherently discloses resistance to imidazolinones. The Office said, for example, "it is clear that imidazolinone resistance is inherent in mutant plants as evidence by the prior art."

It is respectfully submitted that the Office's remarks concerning inherency are misplaced. The doctrine of "inherency" in patent law is quite narrow. The Office has not made the stringent showing that would be required to demonstrate inherency.

M.P.E.P. § 2112, part IV states (citations omitted):

> The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. . . . "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.'" . . .
>
> "In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art."

The Office has not made this stringent showing. An inherent teaching exists only where the missing descriptive matter is a necessary, unavoidable consequence of the express teachings of a cited reference. Inherency may not be established by probabilities, nor possibilities, nor conjecture.

To establish the existence of an allegedly inherent teaching of Terakawa, the Office would need to demonstrate, among other things, that Terakawa's rice plants necessarily, to a 100% certainty, were resistant to the imidazolinone herbicides specified in Claim 62. The Office has not satisfied this strict burden.

The Office cited two secondary references in support of its position. But those references in fact demonstrate precisely the opposite: The secondary references actually show that imidazolinone resistance is not inherent in mutant plants generally, as the Office has apparently asserted.

The Hattori and Bernasconi papers reported that some plants were resistant to one or more imidazolinone herbicides, some plants were resistant to one or more sulfonylurea herbicides, some plants were resistant to both classes of herbicide, and some plants were resistant to neither. These two papers unequivocally refute any contention that resistance to a sulfonylurea herbicide inherently implies that a plant will be resistant to imidazolinone herbicides as well. Following are representative excerpts from these two papers (all internal citations omitted):

> The data illustrate that a multiple-resistance phenotype can be achieved in an AHAS gene through combinations of separate mutations, each of which individually confers resistance to only one class of herbicides. (Hattori, Abstract)

> Since these organisms [*Datura innoxia* and *Chlamydomonas reinhardtii*] contain single AHAS loci, multiple resistance may result from independent mutations within AHAS, each responsible for selective resistance to a specific herbicide class, or from single mutations responsible for cross resistance. To distinguish between these alternatives, cloning of the AHAS genes, DNA sequence analysis and expression in transgenic organisms are needed. (Hattori, p. 167, second column, first full paragraph.)

> Substitutions occurring at Pro 196 in the *N. tabacum* SuRA allele or the analogous Pro 197 site in the *A. thaliana csr1* alleles have been shown to confer selective resistance in sulfonylureas in transgenic tobacco and transgenic *B. napus*. An additional substitution at Trp 573 in the SuRB-Hra allele enhanced the level of resistance to sulfonylureas. (Hattori, p. 167, second column, last paragraph.)

In this study we demonstrate that the substitution at Ser 653 in the *A. thaliana imr*l allele is responsible for selective resistance to the imidazolinones in transgenic plants. (Hattori, p. 168, first column, first full paragraph.)

We also show that a multiple-resistance phenotype can be achieved in single mutant alleles by combining separate mutations which are individually responsible for selective resistance to the sulfonylureas or imidazolinones. (Hattori, p. 168, first column, first full paragraph.)

Seedlings transformed with pCSRIMR containing AHAS with double mutations were resistant to both chlorsulfuron [a sulfonylurea] at 2.8 μM and AC243,977 [imazapyr, an imidazolinone] at 12.5 μM . . . . Seedlings transformed with pIMR were resistant to AC243,977 but not to chlorsulfuron . . . . Previous studies have shown that expression of *csr1* in tobacco confers selective sulfonylurea resistance. (Hattori, p. 172, first column, second paragraph.)

In yeasts, at least ten independent sites within highly conserved regions of AHAS have been mutated to yield sulfonylurea resistance. In this study we demonstrate that a mutation within another conserved region of AHAS is directly responsible for selective resistance to the imidazolinones in the *A. thaliana* mutant GH90. . . . It is likely that mutations at other sites will be found which yield imidazolinone resistance once more mutant AHAS genes are characterized. It is also possible that some of these sites will yield cross resistance to other herbicides. (Hattori, p. 172, paragraph bridging first and second columns.)

The large distance between the mutation at Pro 197 in the *A. thaliana csr1* gene and Ser 653 in the *imr1* gene facilitated the construction of hybrid genes to examine the consequence of combining mutations shown to be responsible for selective herbicide resistance. In transgenic plants, multiple resistance to sulfonylureas and imidazolinones was achieved. (Hattori, p. 172, second column, first full paragraph.)

Acetolactate synthase (ALS) inhibitors . . . fall into four distinct families of compounds: sulfonylureas, imidazolinones, triazolopyrimidine sulfonanilides, and pyrimidinyl oxybenzoates. . . . All the possible point mutations affecting Trp^{552} were investigated by site-directed mutagenesis. Only the Trp –> Leu mutation yielded an active enzyme. This mutation conferred a dramatically reduced sensitivity toward representatives of all four chemical families . . . . (Bernasconi, Abstract)

> The lesion causing tolerance to SU [sulfonylureas] has been localized to a single point mutation affecting proline 197 in ALS in *Arabidopsis thaliana* and position 196 in tobacco. (Bernasconi, p. 17381, second column, second full paragraph)
>
> Two IM [imidazolinone]-specific mutations have been obtained in the laboratory: first, a Ser^{653} –> Asp change in the ALS gene of *A. thaliana* and second, an Ala^{56} –> Thr mutation in corn. (Bernasconi, p. 17381, second column, second full paragraph)
>
> We have cloned and sequenced the mutated gene from two field isolates of cocklebur . . . . The first isolate . . . showed specific tolerance to IM. The second isolate . . . showed high level and broad based tolerance to all classes of ALS inhibitors. (Bernasconi, paragraph bridging pp. 17381 and 17382)
>
> Our study demonstrates that a single point mutation in the ALS gene, Trp^{552} –> Leu, can confer to a weed a broad based and high level of tolerance to all the chemical families of inhibitors.

Additional examples from the cited papers could be given. These excerpts should suffice to demonstrate that all combinations of herbicide resistance and sensitivity have been observed: **(1)** Some plants are sensitive to both imidazolinones and sulfonylureas. **(2)** Some plants are sensitive to imidazolinones, but resistant to sulfonylureas. **(3)** Some plants are sensitive to sulfonylureas, but resistant to imidazolinones. **(4)** Some plants are resistant to both imidazolinones and sulfonylureas, as the result of a single point mutation that provides resistance to both classes of compounds. **(5)** Some plants are resistant to both imidazolinones and sulfonylureas, as the result of double mutations to provide separate avenues for the two types of resistance. **(6)** And undoubtedly further combinations would be found if one also included additional chemical families of AHAS-acting herbicides, other than just imidazolinones and sulfonylureas.

The observation that a plant is resistant to sulfonylurea herbicides does not imply that the plant necessarily possesses inherent resistant to imidazolinone herbicides as well.

M.P.E.P. § 2112 cautions that the observation that a certain result or characteristic may occur, or that it may be present in the prior art does not establish the inherency of that result or characteristic. To establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily, inevitably present in the thing described in the reference. Inherency may not be established by probabilities, nor possibilities, nor conjecture. The mere fact that a certain result may sometimes occur is not sufficient. In relying upon the doctrine of inherency, the Office must demonstrate that the allegedly inherent characteristic necessarily flows from the teachings of the cited reference. The Hattori and Bernasconi papers clearly show that this is not the case. The Office has not established inherency.

The prior art rejections were based on an alleged inherent teaching of Terakawa. The doctrine of inherency is very narrow. The references cited by the Office clearly demonstrate that resistance to imidazolinone herbicides is not, in fact, an inherent characteristic of plants that are resistant to sulfonylurea herbicides. Inherency has not been demonstrated.

It is respectfully submitted that the prior art rejections should be withdrawn.

6. The Obviousness-Type Double Patenting Rejection

Claim 62 was rejected for obviousness-type double patenting over Claim 11 of the issued 6,943,280 patent.

Applicant has previously indicated a willingness to file a terminal disclaimer over the '280 patent, once the Office has indicated that the present application is otherwise in condition for allowance.

The Office has said that this ground of rejection cannot be held in abeyance. (April 9, 2007 Office Action, p. 4).

It would be premature to file a terminal disclaimer at this time. It is possible that the Claims might be amended further before this case is allowed, and it is

possible that Applicant's willingness to file a terminal disclaimer could change in view of any such amendments.

Applicant remains willing to file the proffered terminal disclaimer, once the Office has indicated that all Claims as currently written are otherwise in condition for allowance.

More specifically, in the interest of expediting prosecution, if the Office agrees that the Claims are now otherwise in condition for allowance, then the Examiner is respectfully requested to telephone the undersigned before preparing a further office action or other written communication. The undersigned will then undertake to submit a terminal disclaimer promptly via the PAIR online system, so that the terminal disclaimer may be considered by the Examiner without further delay.

A Same Invention-Type (Statutory) Double Patenting Rejection Should Not Be Entered.

During an August 3, 2007 telephonic interview, the Examiner raised the question of whether he might enter a hypothetical, new ground of rejection in the next office action -- namely, a same invention-type (statutory) double patenting rejection of Claim 62 over Claim 16 of U.S. Patent 6,943,280.

It is respectfully submitted that the present amendments make moot any hypothetical, same invention-type double patenting rejection, and that such a rejection should not be entered.

More specifically, Claim 16 of the '280 patent expressly covers both hybrids and varieties. See part (c) of Claim 16 of the '280 patent. By contrast, Claim 62 of the present application has been amended to refer to hybrids, but not to varieties. Thus these two Claims have differing scope, and a hypothetical same invention-type double patenting rejection would be inappropriate.

If any difference in substance exists between the two Claims in question, then a same invention-type (statutory) double patenting rejection is precluded. See M.P.E.P. § 804, subpart II(A), second paragraph:

> Is there an embodiment of the invention that falls within the scope of one claim, but not the other? If there is such an embodiment, then identical subject matter is not defined by both claims and statutory double patenting would not exist. For example, the invention defined by a claim reciting a compound having a "halogen" substituent is not identical to or substantively the same as a claim reciting the same compound except having a "chlorine" substituent in place of the halogen because "halogen" is broader than "chlorine."

Similarly, new Claim 96 of the present application refers to varietals, but not to hybrids. Thus it also has a different scope from Claim 16 of the '280 patent, and a hypothetical same invention-type double patenting rejection would be inappropriate for it as well.

Interview Summary

A telephonic interview was conducted on August 3, 2007 between Examiner Kruse and the undersigned. The following summary is presented in compliance with M.P.E.P. § 713.04:

(A) There were no exhibits or demonstrations. An earlier draft of the present Request for Continued Examination had been faxed in advance for the Examiner's review. A revised draft of the RCE was also faxed shortly after the interview.

(B) Claim 62 was discussed.

(C) The Terakawa paper and U.S. Patent 6,943,280 were discussed.

(D) No specific amendments were discussed.

(E) Terakawa was discussed very briefly. Most of the discussion, however, concerned U.S. Patent 6,943,280. Initially, the undersigned had

repeated Applicant's general willingness to enter a terminal disclaimer over U.S. Patent 6,943,280, depending on whether any further amendments might be needed to place the Claims in condition for allowance. The Examiner suggested, however, that a new ground of rejection was being considered, a ground of rejection that would not be cured by a terminal disclaimer – namely, a same invention-type (statutory) double patenting rejection against Claim 62 (as amended April 11, 2006) over Claim 16 of U.S. Patent 6,943,280. The undersigned responded that he was unprepared to discuss a new ground of rejection that was not previously reflected in the record. In particular, the claim amendments and related arguments appearing in the present RCE concerning same invention-type double patenting were not discussed during the August 3, 2007 interview.

(F) No other significant matters were discussed.

(G) Agreement was not reached during the interview.

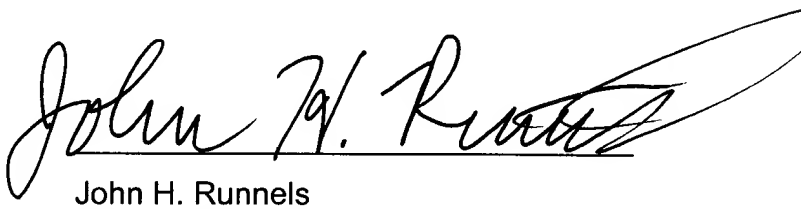
Conclusion

Allowance of all pending Claims at an early date is respectfully requested. The previously withdrawn Claims should now be rejoined, examined, and allowed.

In the alternative, should the Examiner identify any remaining issues, the Examiner is respectfully requested to contact the undersigned to schedule a telephone interview before further action is taken, to discuss whether it might be possible to resolve any such issues quickly, and to conclude the prosecution of this application.

Also, once the Examiner finds the case to be otherwise in condition for allowance, aside from the obviousness-type double-patenting rejection, the Examiner is respectfully requested to telephone the undersigned, so that the double-patenting issue might be resolved expeditiously (e.g., by online submission of a terminal disclaimer) before a further communication is mailed.

Respectfully submitted,



John H. Runnels
Taylor, Porter, Brooks & Phillips, L.L.P.
P.O. Box 2471
Baton Rouge, LA 70821
(225) 381-0257

Registration No. 33,451

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